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COMPARISON OF THE URODYNAMIC EFFICACY OF AN ALPHA-BLOCKER (NAFTOPIDIL) WITH PHYTOTHERAPY (EVIPROSTAT) IN THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA

Aims of Study

Benign prostatic hyperplasia (BPH) is common in men above a certain age throughout the world. Alpha1-adrenoceptor antagonists is widely used as a conservative treatment to relieve bladder outlet obstruction due to benign prostatic enlargement. Naftopidil is a newly synthesized alpha1-blocker that has been found to be effective in the treatment of BPH. This drug is highly selective for the $Alpha1_A$-, and $Alpha1_D$-adrenoceptor subtypes, with an affinity for the $Alpha1_D$-adrenoceptor that is 3- and 17-fold higher than that for the $Alpha1_A$- and $Alpha1_B$-adrenoceptors, respectively(1). Phytotherapeutic drugs including pygeum africanum, Serenoa repens, beta-sitosterol, cernilton and eviprostat have also been widely used in the pharmacological treatment of BPH (2). The aim of the present study is to compare the efficacy of alpha-blocker (naftopidil) with phytotherapy (eviprostat) in terms of International Prostate Symptom Score (IPSS) and urodynamic parameters including pressure/flow study in the treatment of BPH.

Methods

Forty-nine patients with BPH (mean age 67.9± 7.8 years) were entered into the study. Patients were randomly assigned either to the naftopidil group taking an alpha-blocker, naftopidil (50-75mg/daily, 36patients) or the eviprostat group with phytotherapy (6tab/day, 13 patients). The effectiveness of each therapy was assessed by changes in IPSS, uroflowmetry and urodynamic parameters including pressure/flow study. The efficacy of the treatment was evaluated according to the standard criteria proposed by Homma et al and the International Consultation on BPH, and graded as “excellent”, “good”, “fair”, and “poor”(3,4). Efficacy for IPSS was calculated as pre- to post-treatment scores and efficacy for the QOL score and Qmax as the difference

Results

The mean total IPSS, the total storage and voiding symptom scores, and the QOL score decreased significantly ($p<0.0001$, each) in the naftopidil group, but not in the eviprostat group (TABLE I). The efficacy of naftopidil as measured by improvement in the IPSS was judged as excellent (pre/post ratio ≤ 0.25) in 5 patients (13.9%), good (ratio ≤ 0.50) in 9 (25%), fair (ratio ≤ 0.75) in 11(30.6%) and poor (ratio >0.75) in 11(30.6%). No patient in the eviprostat group was judged as excellent or good, and 4 patients (30.8%) were judged as fair and 9 (69.2%) as poor in terms of the efficacy criteria for IPSS.

The changes in free uroflowmetric parameters and post-void residual before and after the therapy are summarized in Table II. In the eviprostat group, no significant changes in terms of average and maximum flow rates (Qave and Qmax, respectively) as well as post-void residual were noted. In the naftopidil group, voided volume increased significantly from 191.3±85.9ml to 241.6±139.6ml ($p=0.0141$). Qave and Qmax increased significantly ($p=0.0008$ and $p=0.0005$, respectively) and the post-void residual and the percent of residual ($p=0.0090$ and $p=0.0083$, respectively) were decreased significantly in the naftopidil group. The efficacy of naftopidil with regard to Qmax was judged as excellent (post-pre difference $\geq$10ml/sec) in 7 patients (19.4%), good (difference$\geq$5) in 6(16.7%), fair (difference$\geq$2.5) in 6(16.7%) and poor (difference<2.5) in 17(47.2%). However, that for eviprostat was judged as good in only 1 patient (9.1%), fair in 1 (9.1%) and poor in 9(81.8%).

In the eviprostat group, no significant changes were noted in the cystometric parameters. In the naftopidil group, bladder capacity at first desire to void increased significantly ($p=0.0239$), and bladder capacity at strong desire to void and bladder compliance tended to increase ($p=0.0707$ and $p=0.0978$, respectively). In the eviprostat group, detrusor opening pressure tended to decrease ($p=0.0573$). In the naftopidil group, Abrams-Griffiths (A-G) number decreased significantly ($p=0.0422$) and detrusor pressure at maximum flow tended to

decrease (p=0.0865). In the pressure/flow study, the baseline grade in the ICS nomogram was classed as obstructed and equivocal in 11 patients and 1 patient, respectively, in the eviprostat group, and 22 and 2 patients, respectively, in the naftopidil group. After treatment, 7 patients (29%) had improved grades (obstructed to unobstructed in 3, obstructed to equivocal in 2 and equivocal to unobstructed in 2) in the naftopidil group, but only 2 patients (16%) showed improvement (obstructed to equivocal) in the eviprostat group.
Among the 14 patients in the naftopidil group detrusor overactivity disappeared in 21% and cystometric capacity increased in 36%, but no improvement in detrusor overactivity was noted in the eviprostat group.

TABLE I. Changes in urinary symptom scores before and after the therapy

	Eviprostat Group n=13	Naftopidil Group n=36	Inter-group difference P value (Student's t-test)
Total IPSS			
Baseline	16.0±6.9	15.4±5.7	0.9006
Change (pre - post)	-0.4±5.2	5.9±4.3	0.0002*
P value (paired t-test)	>0.9999	<0.0001	

TABLE II. Changes in free uroflowmetric parameters and post-void residual before and after the therapy

Average Flow Rates (ml/sec)	Eviprostat Group	Naftopidil Group	Inter-group difference
Baseline	3.7±2.4	3.9±1.9	0.7896
Change (post - pre)	0.83±2.1	2.0±3.3	0.2604*
P value (paired t-test)	0.2109	0.0008	
Maximum Flow Rates (ml/sec)			
Baseline	8.5±4.4	9.8±4.4	0.3842
Change (post - pre)	0.5±2.9	3.7±5.8	0.0886*
P value (paired t-test)	0.5645	0.0005	
Post void residual (ml)			
Baseline	60.2±68.7	47.9±70.7	0.6156
Change (post - pre)	-5.3±74.1	-28.1±60.9	0.3072*
P value (paired t-test)	0.8182	0.0090	
Percent of residual (%)			
Baseline	26.7±21.9	18.3±17.2	0.1932
Change (post - pre)	-7.5±16.6	-7.8±16.7	0.9625*
P value (paired t-test)	0.1653	0.0083	

Conclusions

Naftopidil appears to be more effective than eviprostat in the treatment of BPH.

References

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